OncoHealth

Short-Acting GCSFs:

Granix (Tbo-filgrastim), Neupogen (filgrastim), Nivestym (filgrastim-aafi), Releuko (filgrastim-ayow), Zarxio (filgrastim-sndz)

Effective Date: 7/1/2023
Revision Date(s): 10/2021
Review Date: 03/18/2023
Policy type: Medical Necessity

Authorizations are for 4 months, after which time they must be reviewed for efficacy, safety, and tolerability.

Zarxio (filgrastim-sndz) is the preferred short-acting GCSFs product and does not require prior authorization. Neupogen (filgrastim), Granix (tbo-filgrastim), Leukine (sargramostim), Releuko (filgrastim-ayow), Nivestym (filgrastim-aafi) are all non-preferred short-acting GCSFs products. Members must have documentation of contraindication, failure, or intolerance to Zarxio prior to approval of a non-preferred product.

Universal Criteria:

- Dose and frequency should be consistent with FDA labeling, NCCN, or indication specific peer-reviewed literature.

Indication Specific Criteria:

Febrile neutropenia prophylaxis following myelosuppressive chemotherapy

- The patient has a solid tumor or a non-myeloid malignancy, **and**
- GCSF is administered 24-72 hours following myelosuppressive chemotherapy; **and**
    - The patient experienced a febrile neutropenic event with prior administration of the same or similar chemotherapy regimen, **or**
    - The patient is receiving dose-dense myelosuppressive chemotherapy, **or**
    - The patient is receiving myelosuppressive chemotherapy with a risk of febrile neutropenia of at least 20%, **or**
    - The patient is receiving myelosuppressive chemotherapy with an intermediate risk of febrile neutropenia of 10-20%, **and** one of the following risk factors:
        - Persistent neutropenia (Absolute Neutrophil Count < 500/mm^3 or < 1000/mm^3 and expected to decline to less than 500/mm^3 within the next 48 hours)
        - Bone marrow involvement by tumor

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        - Liver dysfunction with a total bilirubin > 2 mg/dL
        - Renal dysfunction with a creatinine clearance < 50 mL/min
        - Age > 65 years and receiving full chemotherapy dose intensity
        - History of extensive chemotherapy/radiation therapy
    - The patient is receiving myelosuppressive chemotherapy that has a low risk of febrile neutropenia of <10% **and**
        - Dose reduction is not clinically appropriate; **and**
        - at least two of the following risk factors are present:
            - Persistent neutropenia (Absolute Neutrophil Count < 500/mm^3 or < 1000/mm^3 and expected to decline to less than 500/mm^3 within the next 48 hours)
            - Bone marrow involvement by tumor
            - Liver dysfunction with a total bilirubin > 2 mg/dL
            - Renal dysfunction with a creatinine clearance < 50 mL/min
            - Age > 65 years and receiving full chemotherapy dose intensity
            - History of extensive chemotherapy/radiation therapy

Acute Myeloid Leukemia (AML)

- The patient must be scheduled to receive either induction or consolidation chemotherapy; **or**
- The patient has relapsed/refractory disease and is being treated with cladribine and cytarabine; **or**
- The patient has relapsed/refractory disease and is being treated with fludarabine and cytarabine

Febrile Neutropenia Prophylaxis, in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation

Myelodysplastic Syndromes (MDS)

- Patient's MDS is lower risk (IPSS-R very low, low, or intermediate); **and**
- Patient's serum erythropoietin ≤500 mU/mL; **and**
- In combination with an erythropoiesis-stimulating agent (ESA)

Treatment of Febrile Neutropenia

- The patient must have a diagnosis of febrile neutropenia; **and**
- must be used in adjunct with appropriate antibiotics in high risk members

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Management of Immunotherapy or CAR T-Cell-Related Neutropenia

Wilms Tumor

- Patient is scheduled to receive cyclophosphamide with etoposide; **or**
- Patient is scheduled to receive combination therapy with cyclophosphamide, doxorubicin, and vincristine

Approval Criteria:

Unless otherwise noted above the review criteria used by OncoHealth to determine medical necessity for anticancer treatments and supportive agents include, but is not limited to:

- New drugs or regimens (combinations of drugs) approved by the United States Food and Drug Administration (FDA).
- Drugs and biologics may be used off-label if they are considered medically accepted or necessary if supported by any of the following 5 compendia below.
    - NCCN Drugs & Biologics Compendium® (Category 1 and 2a)
    - Clinical Pharmacology (Strong For)
    - American Hospital Formulary Service Drug Information (AHFS DI) (Level 1)
    - Thompson Micromedex DrugDex® (Class I and IIa)
    - Wolters Kluwer Lexi-Drugs® (Level A)
- Other use of drugs and biologics may be considered medically accepted if supported as safe and effective according to peer-reviewed articles from one of the following journals
    - American Journal of Medicine; Annals of Internal Medicine; Annals of Oncology; Annals of Surgical Oncology; Biology of Blood and Marrow Transplantation; Blood; Bone Marrow Transplantation; British Journal of Cancer; British Journal of Hematology; British Medical Journal; Cancer; Clinical Cancer Research; Drugs; European Journal of Cancer (formerly the European Journal of Cancer and Clinical Oncology); Gynecologic Oncology; International Journal of Radiation, Oncology, Biology, and Physics; The Journal of the American Medical Association, Journal of Clinical Oncology; Journal of the National Cancer Institute; Journal of the National Comprehensive Cancer Network (NCCN); Journal of Urology; Lancet; Lancet Oncology; Leukemia; The New England Journal of Medicine; Radiation Oncology
    - **Meeting abstracts and case reports are excluded from consideration.**
- Non-standard protocols may be approved based on unique clinical circumstances.

Billing Codes

Drug Name	HCPCS Code	Description
Granix	J1447	Injection, tbo-filgrastim, 1 microgram
Neupogen	J1442	Injection, filgrastim (g-csf), excludes biosimilars, 1 microgram
Nivestym	Q5110	Injection, filgrastim-aafi, biosimilar, (nivestym), 1 microgram
Releuko	J3590	Unclassified biologics
Zarxio	Q5101	Injection, filgrastim-sndz, biosimilar, (zarxio), 1 microgram

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References

1. Granix [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; Available at: https://www.granixhcp.com/globalassets/granix-hcp/prescribing-information.pdf. Accessed 03/08/2023
2. Granix. NCCN. Cancer Guidelines and Drugs and Biologics Compendium. Available at: https://www.nccn.org/professionals/drug_compendium/content/. Accessed 03/08/2023
3. Neupogen [package insert]. Thousand Oaks, CA: Amgen Inc.; Available at: https://www.pi.amgen.com/~/media/amgen/repositorysites/pi-amgen-com/neupogen/neupogen_pi_hcp_english.pdf. Accessed 03/08/2023
4. Neupogen. NCCN. Cancer Guidelines and Drugs and Biologics Compendium. Available at: https://www.nccn.org/professionals/drug_compendium/content/. Accessed 03/08/2023
5. Nivestym [package insert]. Lake Forest, IL: Hospira, Inc.; Available at: http://labeling.pfizer.com/ShowLabeling.aspx?id=10899. Accessed 03/08/2023
6. Nivestym. NCCN. Cancer Guidelines and Drugs and Biologics Compendium. Available at: https://www.nccn.org/professionals/drug_compendium/content/. Accessed 03/08/2023
7. Releuko [package insert]. Kashiv BioSciences, LLC Piscataway, NJ; Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761082s000lbl.pdf. Accessed 03/08/2023
8. Zarxio [package insert]. Princeton, NJ: Sandoz Inc.; Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=c0d1c22b-566b-4776-bdbf-00f96dad0cae. Accessed 03/08/2023
9. Zarxio. NCCN. Cancer Guidelines and Drugs and Biologics Compendium. Available at: https://www.nccn.org/professionals/drug_compendium/content/. Accessed 03/08/2023
10. Hematopoietic Growth Factors: NCCN Clinical Practice Guidelines in Oncology Version 2.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/growthfactors.pdf. Accessed 03/08/2023
11. Acute Myeloid Leukemia: NCCN Clinical Practice Guidelines in Oncology Version 1.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/growthfactors.pdf. Accessed 03/08/2023
12. Myelodysplastic Syndromes: NCCN Clinical Practice Guidelines in Oncology Version 1.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/growthfactors.pdf. Accessed 03/08/2023

Disclaimer

Consideration of medically necessary indications are based upon U.S. Food and Drug Administration (FDA) indications, recommended uses within the Centers of Medicare & Medicaid Services (CMS) five recognized compendia, including the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium (Category 1 or 2A recommendations), and peer-reviewed scientific literature eligible for coverage according to the CMS, Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 titled, "Off-Label Use of Anti-Cancer Drugs and Biologics." This policy evaluates whether the drug therapy is proven to be effective based on published evidence-based medicine. OncoHealth reserves the right to request medical documentation as needed to validate medical necessity determinations.

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Drug Coverage Policies are developed as needed, regularly reviewed, updated at least annually, and are subject to change. Other policies and coverage determination guidelines may apply. Federal and state regulatory requirements and member specific benefit plan documents, if applicable, must be reviewed prior to this Drug Coverage Policy. This Drug Coverage Policy is for informational purposes only and does not constitute medical advice or dictate how providers should practice medicine. This policy should not be reproduced, stored in a retrieval system, or altered from its original form without written permission from OncoHealth, Inc.

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